Exhibit C

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EXAMINER	
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ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/903,587	KEARNS ET AL.	
	Examiner	Art Unit	
	STEPHANIE K. MUMMERT	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2012*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1,4 and 6-17* is/are pending in the application.

5a) Of the above claim(s) *13-16* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,4,6-12 and 17* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on March 14, 2012 is acknowledged and has been entered. Claims 1, 10 and 11 have been amended. Claims 2-3 and 5 have been canceled. Claim 17 has been newly added. Claims 1, 4, 6-12 and 17 are pending. Claims 13-16 are withdrawn from consideration as being drawn to a non-elected invention.

Claims 1, 4, 6-12 and 17 are discussed in this Office action.

All of the amendments and arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons discussed below. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This action is made FINAL as necessitated by Amendment.

Claim Interpretation

The term "genomic dataset" is not explicitly defined in the specification. Therefore, the term is being given the broadest reasonable interpretation in light of the specification. The term is referred to "All data for each sample at all quality control checkpoints are associated with the relevant genotype dataset and the DATA IS TRANSPORTED TO A SECURE OFF SITE SERVER FARM (paragraph 125)". Therefore, the term will be interpreted as reading on the process of analyzing the results to achieve data regarding the genomic sequence.

The term "high resolution map" is not explicitly defined in the specification. Therefore, the term is being given the broadest reasonable interpretation in light of the specification. The term is referred to "Another object is to determine a high-resolution amplification and/or deletion map to identify nucleotide sequences that may be associated with cancer and/or other genetic conditions (paragraph 41)". Therefore, the term will be interpreted as reading on an identification of nucleotide sequence(s) as recited.

New Grounds of Rejection necessitated by Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 6-12 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al. (Molecular Human Reproduction, 2004, 10(4):283-289; epub January 2004), Thornhill et al. (Human Reproduction, 2005, epub, November 11, 2004; 20(1):35-48), Zollner et al. (Human Reproduction, 2002, 17(5):1327-1333) and Dean et al. (PNAS, 2002, 99(8):5261-5266).

With regard to claim 1, Hu teaches a method for interrogating the content and primary structure of genomic (nuclear) and mitochondrial DNA (mtDNA) in human embryos for comprehensive genetic screening and diagnosis using a microarray, comprising the steps of:

extracting the DNA (p. 283, col. 2, where chromosome specific libraries were amplified);
amplifying said DNA by amplification employing polymerase in a solution having total volume of between 40-750 ul (p. 283, col. 2, where chromosome specific libraries were amplified in a total volume of 50 ul; p. 284, col. 1, where single cells were amplified by whole genome DOP-PCR in a total volume of 50 ul);
screening said amplified DNA for aneuploidy and structural chromosome abnormalities using a genotyping microarray (Table I, where the cells were screened by array CGH);
imaging said genotyping microarray for the DNA of each of said single cells and associating said image with said individual identifier (Figure 1, where the array was imaged for binding to the samples); and
analyzing said genotyping microarray images to screen for genetic abnormalities in each of said cells (Figure 1, where the array was imaged for binding to the samples; Table I, where the cells were screened by array CGH)).

With regard to claim 10, Hu teaches a method for isolating and amplifying DNA from single cells to run a modified microarray platform in:

transferring a single cell for genetic analysis (p. 284, col. 1, where single cells were amplified by whole genome DOP-PCR in a total volume of 50 ul);

amplifying, in a solution having total volume of between 40-750 ul, DNA from said single cell by an optimized whole genome amplification reaction employing polymerase (p. 284, col. 1, where single cells were amplified by whole genome DOP-PCR in a total volume of 50 ul);

purifying the amplified DNA (p. 284, col. 2, where the labeled amplified products were purified using UltraClean);

assaying the purified/amplified DNA by high-density microarray interrogation of naturally occurring DNA sequences to yield a genomic dataset (Table I, where the cells were screened by array CGH; Figure 1, where the array was imaged for binding to the samples);

interrogating the genomic dataset and generating a high-resolution map (Figure 3, where the ratio between the two separate labels are measured for each chromosome).

With regard to claim 6, Hu teaches a method according to claim 1, further comprising purifying the amplified DNA (p. 284, col. 2, where the labeled amplified products were purified using UltraClean).

With regard to claim 7, the method according to claim 1, wherein said step of performing pre-implantation genetic diagnosis and screening further comprises the substeps of:

assaying the amplified DNA by high-density microarray interrogation of naturally occurring DNA sequences to yield a genomic dataset (Table I, where the cells were screened by array CGH; Figure 1, where the array was imaged for binding to the samples),

interrogating the genomic dataset and generating a high-resolution map (Figure 3, where the ratio between the two separate labels are measured for each chromosome).

With regard to claim 8, Hu teaches a method according to claim 7, further comprising a substep of using fluorescence in situ Hybridization (FISH) to identify chromosome aberrations (p. 285, col. 1, where FISH was carried out on the samples with results not shown.

Regarding claim 1, while Hu generally teaches that the technique of array interrogation can be applied in PGD, Hu doesn't specifically teach the steps of fertilizing human ova in vitro, grading embryos, biopsying the embryos, extracting DNA from blastomere or trophectoderm cells or working in a first sterile laboratory maintained at a positive pressure relative to ambient atmospheric conditions. Regarding claim 10, Hu does not teach creating, evaluating, grading embryos or extracting DNA from blastomere or trophectoderm cells.

With regard to claim 1, Thornhill teaches working in a first sterile laboratory maintained at a positive pressure relative to ambient atmospheric conditions;

fertilizing human ova in vitro with human sperm and growing said fertilized human ova (zygotes) in a culture medium to embryonic stage (p. 40, where ICSI fertilization is recommended for PGD cases);

biopsying said individually identified embryos by removal of at least one blastomere or trophectoderm cell and storing said at least one biopsied cell from each embryo in an opaque assaying tube marked with the corresponding individual identifier of the embryo from which it was biopsied (p. 40, where biopsy timing and cell removal procedures are suggested; and where blastomere cell is removed from cleavage stage embryos and where trophectoderm cells are removed from blastocysts and where it is emphasized that embryos should be identified and handled individually);

extracting DNA of said blastomere or trophectoderm cells of each embryo (p. 44, where cells are washed and placed into PCR tubes; p. 42, where tests should be validated on lymphocytes or buccal cells and should also be performed on blastomere cells as well; p. 36, col. 2, where lysis for single cell PCR can vary);

moving said assaying tubes through a first portal maintained at a pressure lower than the pressure of said first sterile laboratory (p. 43-44 "work practice controls", where there should be "physical separation of the pre-PCR, PCR and post-PCR laboratories and the biopsy laboratory" and where PCR should be performed in a "positive pressure room or class II hood" and where it is advised that surfaces and equipment should be treated for decontamination);

illuminating said assaying tubes with ultraviolet light while in said first portal for decontamination, and transferring said assaying tubes from said first portal to a second sterile laboratory maintained at a positive pressure relative to ambient atmospheric conditions;

in said second sterile laboratory (p. 43, col. 2, where UV treatment can be included; p. 43-44 "work practice controls", where there should be "physical separation of the pre-PCR, PCR and post-PCR laboratories and the biopsy laboratory" and where PCR should be performed in a "positive pressure room or class II hood" and where it is advised that surfaces and equipment should be treated for decontamination),

moving said assaying tubes containing said amplified DNA through a second portal maintained at a pressure lower than the pressure of said second sterile laboratory;

illuminating said assaying tubes with ultraviolet light while in said second portal for decontamination, transferring said assaying tubes containing said amplified DNA to a third sterile laboratory (p. 43-44 "work practice controls", where there should be "physical separation

of the pre-PCR, PCR and post-PCR laboratories and the biopsy laboratory" and where PCR should be performed in a "positive pressure room or class II hood" and where it is advised that surfaces and equipment should be treated for decontamination);

in said third sterile laboratory, screening said amplified DNA for aneuploidy and abnormalities and analyzing and selecting at least one genetically normal embryo likely to achieve a successful implantation and viable pregnancy, and communicating to said first laboratory the individual identifier of said at least one selected embryo (p. 44, "protocols" and "analysis of PCR results" heading, where the results of DNA amplification are analyzed for aneuploidy and abnormality and selection of viable embryos is the next step; p. 46, "embryo selection" heading, where cell number, growth and morphology are included in the evaluation criteria).

With regard to claim 4, Thornhill teaches a method according to claim 1, wherein said step of embryo biopsy comprises transferring a single blastomere or trophectoderm cell from a viable embryo for genetic analysis (p. 40, where biopsy timing and cell removal procedures are suggested; and where blastomere cell is removed from cleavage stage embryos and where trophectoderm cell is removed from blastocysts and where it is emphasized that embryos should be identified and handled individually).

With regard to claim 9, Thornhill teaches a method according to claim 1, comprising a final step of transferring said at least one preferred embryo to the patient (p. 44, where the process of transfer of embryo to patient is described in detail).

With regard to claim 10, Thornhill teaches fertilizing human ova in vitro with human sperm under sterile laboratory conditions (p. 40, where ICSI fertilization is recommended for PGD cases);

growing said fertilized human ova (zygotes) in an embryo culture for 2-8 days (p. 40, col. 1, where the embryos are cultured for up to three or more days before biopsy);

on said third day, visually assessing said zygotes with a microscope and grading based on pre-defined morphological criteria (p. 45, col. 1, where embryo selection includes visual inspection of cell number, cell activity and morphology);

biopsying viable embryos (p. 40, where biopsy timing and cell removal procedures are suggested; and where blastomere cell is removed from cleavage stage embryos and where trophectoderm cells are removed from blastocysts and where it is emphasized that embryos should be identified and handled individually);

double washing said single blastomere or trophectoderm cell in a calcium and magnesium free phosphate buffered saline transferring a blastomere or trophectoderm cell from said viable embryo for genetic analysis (p. 44, col. 1, where blastomeres are washed at least twice before transfer for genetic analysis; p. 39, col. 2, where the phosphate buffered saline is Calcium and Magnesium free);

sorting said embryos by cell stage into separate wells based on said criteria (p. 45, col. 1, where embryo selection includes visual inspection of cell number, cell activity and morphology); to determine a selected subset; transferring the selected subset of graded embryos to patient (p. 44, where the process of transfer of embryo to patient is described in detail).

Regarding claim 1, while Thornhill discusses evaluating embryos post biopsy during embryo selection (p. 46, col. 1) neither Hu nor Thornhill teach specifically grading said embryos based on objective morphological criteria including degree of expansion, inner cell mass (ICM) and trophectoderm (TE), and based on a subjective visual inspection via light microscopy, and

assigning to each of said embryos that meet said criteria an individual identifier. Regarding claim 10, neither Hu nor Thornhill teach on said third day, visually assessing said zygotes with a microscope and grading based on pre-defined morphological criteria.

With regard to claim 1 and 7, Zollner teaches grading said embryos based on objective morphological criteria including degree of expansion, inner cell mass (ICM) and trophectoderm (TE), and based on a subjective visual inspection via light microscopy, and assigning to each of said embryos that meet said criteria an individual identifier (p. 1328, col. 2 "blastocyst culture heading, where multiple aspects are evaluated in assigning a grade to an embryo. For example, "1 = fully expanded blastocyst (distinct inner cell mass, trophectoderm and blastocele, thin zona pellucida, fully expanded diameter).

With regard to claim 10, Zollner teaches grading embryos by subjective visual inspection using light microscopy based on objective morphological criteria including degree of expansion, inner cell mass (ICM) and trophectoderm (TE), and sorting said embryos by cell stage into separate wells based on said criteria; to determine a selected subset; transferring the selected subset of graded embryos to patient (p. 1328, col. 2 "blastocyst culture heading, where multiple aspects are evaluated in assigning a grade to an embryo. For example, "1 = fully expanded blastocyst (distinct inner cell mass, trophectoderm and blastocele, thin zona pellucida, fully expanded diameter; p. 1329, col. 1, where no more than three embryos were transferred to patient).

With regard to claim 12, Zollner teaches a method according to claim 11, wherein said step of assessing said zygotes with a microscope and grading embryo cleavage includes >2 cells of cleaving embryos (p. 1328, col. 2, where cleavage speed and cleavage stage are evaluated).

Neither Hu nor Thornhill nor Zollner teach amplifying said DNA by multiple displacement amplification using the specific limitations regarding the concentration of phi 29 polymerase as claimed.

With regard to claim 1 and 10, Dean teaches amplifying said DNA by multiple displacement whole genome DNA amplification employing 800-1000 units/ml phi29 phage polymerase (p. 5261, col. 2, "amplification of human genomic DNA" heading, where the reaction includes 800 units/ml of phi29 phage polymerase).

With regard to claim 11, Dean teaches the method for isolating and amplifying DNA from single cells according to claim 10, wherein said step of amplifying DNA from said single blastomere or trophectoderm cell by an optimized multiple displacement amplification reaction employing phi29 phage polymerase includes the substep of incubation of said solution for a period of between two and twenty hours at a temperature of from 29-33°C (p. 5261, col. 2, "amplification of human genomic DNA" heading where the reactions were incubated for 18 hours at 30 degrees C).

With regard to claim 17, Dean teaches the method for isolating and amplifying DNA from single cells according to claim 11, wherein said step of amplifying DNA from said single blastomere or trophectoderm cell by an optimized whole genome amplification reaction employing phi29 phage polymerase includes the substeps amplification by multiple displacement amplification employing phi29 phage polymerase for an incubation period of four hours followed by amplification by whole genome amplification employing phi29 phage polymerase for an incubation period of thirteen hours (p. 5261, col. 2, "amplification of human genomic DNA" heading where the reactions were incubated for 18 hours at 30 degrees C).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have extended the teachings of Hu to include the specific and detailed suggestions of particular steps to include in IVF and PGD analysis as taught by Thorhill to arrive at the claimed invention with a reasonable expectation for success. As taught by Thornhill, "the ESHRE PGD Consortium undertook to draw up guidelines aimed at giving information, support and guidance to potential, fledgling and established PGD centres. The success of a PGD treatment cycle is the result of great attention to detail. We have strived to provide a similar level of detail in this document and hope that it will assist staff in achieving the best clinical outcome for their patients" (Abstract). Thornhill also notes "PGD and PGS are treatment options that are relatively unregulated and lack standardization compared with other forms of diagnostic testing" (p. 46, col. 2). Therefore, while Thornhill may not particularly refer to a lab at a particular step in the method as first, second, or third lab, Thornhill included enough detail that their teaching could be easily extrapolated to include the particular first, second and third lab as suggested by Thornhill into the method of array based evaluation as a part of pre-implantation genetic diagnosis as suggested by Hu to arrive at the claimed invention with a reasonable expectation for success.

Furthermore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have adjusted the teachings of Hu and Thornhill to include the specific steps of grading of embryos as taught specifically by Zollner to arrive at the claimed invention with a reasonable expectation for success. First, it is noted that while Hu does not specifically teach the grading, biopsy or extraction of genetic material from embryos, Hu does teach, "The advantage of our method is that it takes only 30 h to perform, making it applicable to

PGD for aneuploidy screening, allowing embryo transfer to occur in the fresh IVF cycle. Microarray CGH is easier to perform than single cell metaphase CGH and is more amenable to automation. Compared to single cell FISH, microarray CGH may allow a concomitant diagnosis for single gene disorders, providing the PGD patient at high risk of genetic disorders such as cystic fibrosis with specific information about their genotype as well as information about aneuploidy" -p. 287, col. 2 to 288, col. 1). Further, while Hu teaches amplification and array analysis in lymphocyte cells, Thornhill notes "It is recommended that single lymphocytes, lymphoblastoid cell lines, fibroblasts or buccal cells (or any somatic cell type with appropriate validation) are used to validate the assay at the single cell level. Testing of blastomeres would be beneficial, as these are the target cells, but this will depend on availability" (p. 42, col. 2). Regarding embryo evaluation, Thornhill also teaches, "The following post-biopsy criteria are recommended to facilitate embryo selection: diagnosis of unaffected status, cell number pre- and post-biopsy, evidence of active cell division post-biopsy and embryo morphology pre- and post biopsy" (p. 45, col. 1, "embryo selection" heading). Thornhill also teaches "it is recommended to set criteria prior to performing clinical PGD and adhere to them" (p. 40, col. 2). In line with this suggestion, Zollner teaches, "the use of this scoring system allows selection of those zygotes with favourable developmental potential for further embryo culture, therefore maximizing the chance of implantation" (p. 1328, col. 1). Therefore considering the particular suggestions in Hu, Thornhill and Zollner regarding embryo evaluation and scoring, it would have been obvious to one of ordinary skill to have incorporated each of these teaches into the method as taught by Hu and Thornhill to arrive at the claimed invention with a reasonable expectation for success.

Furthermore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the teachings of multiple displacement amplification as taught by Dean into the method of embryo evaluation, array hybridization and pre-implantation genetic diagnosis as taught by Hu, Thornhill and Zollner to arrive at the claimed invention with a reasonable expectation for success. While Hu teaches whole genome amplification using "random whole genome amplification of single cells using DOP-PCR" (p. 284, col. 1), Dean specifically draws a connection and comparison between different techniques of whole genome amplification including multiple displacement amplification and DOP-PCR (Table 1, where amplification yield was examined and compared between samples amplified by DOP-PCR, MDA and PEP PCR). As taught by Dean, "The amplification is surprisingly uniform across the genomic target, with the relative representation of different loci differing by less than 3-fold. In contrast, PCR-based WGA methods exhibited strong amplification bias ranging from 4 to 6 orders of magnitude. Multiple displacement amplification (MDA)-generated DNA product is >10 kb, and its performance is demonstrated for a variety of applications, including single nucleotide polymorphism (SNP) analysis, restriction fragment length polymorphism (RFLP), and comparative genome hybridization. MDA was capable of accurate WGA from <10 human cells" (p. 5261, col. 1-2). Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to have incorporated the teachings of multiple displacement amplification as taught by Dean into the method of embryo evaluation, array hybridization and pre-implantation genetic diagnosis as taught by Hu, Thornhill and Zollner to arrive at the claimed invention with a reasonable expectation for success.

Response to Arguments

Applicant's arguments with respect to claims 1, 4, 6-12 and 17 have been considered but are moot because the arguments do not apply to any of the references being used in the current rejection.

Conclusion

No claims are allowed. All claims stand rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEPHANIE K. MUMMERT whose telephone number is (571)272-8503. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/STEPHANIE K MUMMERT/

Primary Examiner, Art Unit 1637